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08/113,561	08/25/1993	THOMAS R. ADAMS	DEKA055	3079

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EXAMINER

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**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Application Number: 08/113,561
Filing Date: August 25, 1993
Appellant(s): ADAMS ET AL.

Robert E. Hanson
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 24 July 2006 appealing from the Office action mailed 26 January 2005, which appeal brief is further in response to the Notice of Non-Complaint Appeal Brief of 26 June 2006.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The following are the related appeals, interferences, and judicial proceedings known to the examiner which may be related to, directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal:

Appealed Application No. 09/732,439 entitled "Transgenic Maize With Increased Mannitol Content" is commonly owned with the instant application on appeal, shares inventors Paul Anderson and Paul Chomet, is a continuation-in-part of a divisional of the instant application, and claims a maize plant transformed with another foreign gene.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

No amendment after final has been filed.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

A substantially correct copy of appealed claims 2-4 and 67 appears on page 15 of the Appendix to the appellant's brief. The minor errors are as follows:

In claims 2 and 3, ---or 68--- should appear after "67".

Appellant's intent to amend these claims to delete the recitation of cancelled claim 68 is noted (see page 3 of the Brief of 24 July 2006). However, the claims currently recite cancelled claim 68.

(8) Evidence Relied Upon

Stephanopoulos et al. "Metabolic engineering--methodologies and future prospects", Trends in Biotechnology, Vol. 11 (September 1993), pp. 392-396.

Post-Beittenmiller et al. "Expression of Holo and Apo Forms of Spinach Acyl Carrier Protein-I in Leaves of Transgenic Tobacco Plants", The Plant Cell, Vol. 1 (September 1989), pp. 889-899.

Fox et al. "Stearoyl-acyl carrier protein delta 9 desaturase from Ricinus communis is a diiron-oxo protein", Proceedings of the National Academy of Sciences USA, Vol. 90 (March 1993), pp. 2486-2490.

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

35 USC 112(1): Written Description

Claims 2-4 and 67 on appeal stand rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to

reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims *are broadly drawn to* the genus of fertile maize plants transformed with *the genus of any gene encoding any fatty acid desaturase enzyme*, wherein the enzymes and genes are from any source, including plant, bacteria, fungi or animals; wherein the enzymes and genes are of any sequence; and wherein any desaturase enzyme having any fatty acid as a substrate is contemplated. In other words, fatty acid desaturase enzymes may act at various positions in the fatty acid, such as delta-6, delta-9, delta-12, delta-16, etc. Furthermore, different types of desaturases may act on different types of fatty acids with different lengths of carbon backbone and different side group constituents. Different types of desaturases may also act on many different fused compounds containing them, such as acyl carrier protein-bound fatty acids. It is noted that a gene encoding a fatty acid desaturase enzyme is an *essential feature* of the claimed invention. The claims specify that the transformed maize plants actually exhibit a phenotypic characteristic (i.e. morphological trait) as a result of the presence and expression of the introduced fatty acid desaturase gene, which phenotypic characteristic is sufficient to distinguish such plants from those which do not contain the gene.

In contrast, the specification *does not reduce even a single species of the claimed genus to practice*. The specification does not provide guidance for the isolation or identification of even a single gene from a single source and of a single sequence which encodes any fatty acid desaturase. The specification does not provide guidance for plant transformation with any fatty acid synthesis gene. The specification merely

lists enzymes thought to be involved in fatty acid synthesis including fatty acid desaturase on page 45, lines 27-29, and suggests plant transformation therewith:

“Alternatively DNA sequences may be introduced which slow or block steps in fatty acid biosynthesis resulting in the increase in precursor fatty acid intermediates. Genes that might be added include desaturases...”

The specification does not even recite other publications which teach genes encoding such enzymes, and does not attempt to incorporate by reference their teachings.

Thus, the specification *does not provide any relationship between structure (gene or enzyme sequence) and function (enzyme activity or phenotypic change at the whole plant level)*. Furthermore, the specification *does not provide even one species* in an attempt to describe or represent the claimed genus.

It is noted that none of the parent applications list any enzyme involved in grain composition or fatty acid synthesis, or suggest maize plant transformation therewith. Accordingly, the effective filing date for maize transformed with the instantly claimed fatty acid desaturase genes is the filing date of the instant application, namely 25 August 1993. The effective filing date for maize transformation in general, using microprojectile bombardment, is 17 April 1990, the filing date of the earliest parent application which disclosed this feature.

The Federal Circuit has recently clarified the application of the written description requirement. The court stated that a written description of an invention “requires a precise definition, such as by structure, formula, [or] chemical name, of the claimed subject matter sufficient to distinguish it from other materials.” *University of California v. Eli Lilly and Co.*, 119 F.3d 1559, 1568; 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). The court also concluded that “naming a type of material generally known to exist, in the

absence of knowledge as to what that material consists of, is not a description of that material.” Id. Further, the court held that to adequately describe a claimed genus, Patent Owner must describe a representative number of the species of the claimed genus, and that one of skill in the art should be able to “visualize or recognize the identity of the members of the genus.” Id.

See MPEP Section 2163, page 194 of Chapter 2100 of the October 2005 version, bottom paragraph, where it is taught that

[T]he claimed invention as a whole may not be adequately described where an invention is described solely in terms of a method of its making coupled with its function and there is no described or art-recognized correlation or relationship between the structure of the invention and its function. A biomolecule sequence described only by a functional characteristic, without any known or disclosed correlation between that function and the structure of the sequence, normally is not a sufficient identifying characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence.

Given the claim breadth and lack of guidance as discussed above, wherein the specification fails to provide any written description of even a single species (a fatty acid desaturase enzyme or gene encoding it, to be inserted into a transformed maize plant), the specification fails to provide an adequate written description of the genus as broadly claimed (maize plants transformed with the genus of sequences of any and all fatty acid desaturase enzymes and any and all genes encoding them). Accordingly, one skilled in the art would not have recognized Applicant to have been in possession of the claimed invention at the time of filing. See the Written Description Requirement guidelines published in Federal Register/ Vol. 66, No. 4/ Friday January 5, 2001/ Notices: pp. 1099-1111.

See also *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ 2d 1016 at 1021, (Fed. Cir. 1991) where it is taught that a gene is not reduced to practice until the inventor can define it by "its physical or chemical properties" (e.g. a DNA sequence).

See also *University of California v. Eli Lilly and Co.*, 43 USPQ2d 1398 (Fed. Cir. 1997), which teaches that the disclosure of a process for obtaining cDNA from a particular organism and the description of the encoded protein fail to provide an adequate written description of the actual cDNA from that organism which would encode the protein from that organism, despite the disclosure of a cDNA encoding that protein from another organism.

See also *University of Rochester v. G.D. Searle & Co., Inc.*, 68 USPQ2d 1424, 1433 (DC WNY 2003), which teaches that method claims are properly subjected to a written description rejection if the starting material required by that method is itself inadequately described.

Furthermore, an assay for *finding* a product is not equivalent to a positive recitation of *how to make* a product. Alternatively, disclosure of a method for producing a product does not reduce to practice the product itself. See *Bayer v. Housey*, 68 USPQ2d 1001, 1008-1009 (Fed. Cir. 2003): "processes of identification and generation of data are not steps in the manufacture of a final [drug] product".

Appellant's Arguments

Appellant urges that the Examiner has improperly examined the claims as if they were drawn to fatty acid desaturase genes rather than plants transformed therewith. Appellant further refutes the Examiner's position via the following arguments: the lack of a requirement that the specification include what is well-known and publicly available,

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the inapplicability of the cited case law to the instant fact pattern, the availability of fatty acid desaturase genes prior to August 1993 as evidenced by references appended to the Response of 18 October 2004, the discussion in the specification of how altered fatty acid composition would affect grain quality phenotype, and the successful prior expression of other transgenes in maize (see pages 3-10 of the Brief of 24 July 2006). The Examiner submits that Appellant's arguments are not persuasive.

The Examiner is not interpreting the claims as if they were drawn to genes *per se*, as clearly stated above and previously. The Examiner is, however, interpreting the claims as being drawn to plant products which contain introduced genetic sequences, which sequences were inadequately described, thus rendering the plants containing them inadequately described. Furthermore, the Examiner notes that the Written Description Guidelines support his position, that claims drawn to products containing inadequately described components are themselves inadequately described. Appellant is also directed to *University of Rochester* which teaches that claim construction is arbitrary, and that any claim involving an inadequately described starting material is itself inadequately described.

Regarding the state of the art, the Examiner disagrees that fatty acid desaturase genes were well-known and publicly available prior to Appellant's invention, particularly throughout the broadly claimed genus of any gene of any sequence from any organism encoding any type of fatty acid desaturase protein of any sequence, as stated above and as discussed below. Furthermore, the Examiner disagrees that the genus of transformed corn plants was well-known and publicly available prior to Appellant's

invention. As urged by Appellant, it is the transformed maize plants which are novel and which are being claimed.

Regarding the case law, the Examiner maintains that all cited case law supports his position. In *Amgen*, the claims were not limited to isolated genes. Instead, the claims included *compositions* comprising the proteins encoded by those genes. See claims 3 and 6 of US 4,677,195 owned by Genetics Institute, which are directed to *pharmaceutical compositions* comprising particular erythropoietin proteins which would be inherently encoded by particular genes. In *Amgen*, the Court found that claims 3 and 6 were invalid. As admitted by Appellant, this finding was due to the inadequate conception of a particular nucleic acid sequence (see paragraph bridging pages 4 and 5 of the Brief of 24 July 2006). Similarly, in the instant situation, Appellant has not conceived of any particular nucleic acid sequence, so that *compositions* containing them, *i.e. transformed plants*, are inadequately described.

Similarly, in *Lilly*, the invalidated claims of US 4,652,525 included claims drawn to *compositions* containing isolated DNA, *i.e.* plasmids containing the DNA, and microorganisms containing the plasmids (see, *e.g.*, claims 1 and 2). The Court found that generic claims, drawn to plasmids containing the genus of DNA sequences encoding insulin from any vertebrate (which includes rats, cows, birds, snakes, dogs, cats, humans, etc.), and generic claims drawn to microorganisms containing the plasmids, were each inadequately described. Moreover, the Court found that claims drawn to *compositions comprising a broad genus of sequences* were inadequately described, even *though that genus may include a single particularly described species*

(in that case, the described species was DNA encoding rat insulin). In the instant case, *Appellant has not even reduced to practice or described a single species*, namely a transformed maize plant containing even a single gene of a single sequence encoding a particular fatty acid desaturase enzyme of a particular protein sequence. Following the teachings of *Lilly*, in light of the instant fact pattern which provides no description of even a single species of the claimed genus, the Examiner's position is supported.

In *University of Rochester*, the Court found that patent claims which merely defined a substance "only by a description of its function or the desired result of its use" were inadequately described if "the specification did not provide an adequate written description of the... DNA required by the asserting claims" (see page 1428 of 68 USPQ2d, item B). The Court concluded that the claims of US 6,048,850, drawn to a compound which alleviates pain without other side effects, were inadequately described, since the specification "*does no more than describe the desired function of the compound called for, and ...contains no information by which a person...would understand that the inventors were in possession of the claimed invention*" (see page 1430, item C.) In the instant application, Appellant is claiming the genus of transformed maize plants which comprise a genus of DNA sequences and which exhibit altered morphological traits. In contrast, Appellant has not described even a single species of the genus of DNA sequences, has not reduced to practice even a single maize plant containing a single fatty acid desaturase gene, and has certainly not demonstrated possession of a transformed maize plant containing such a gene which has an altered

morphological trait. Such altered phenotypic characteristics are analogous to the "desired result of its use" prohibited by the Court.

In *Bayer*, the Court dismissed Housey's counterclaim of infringement, since the Housey patent had merely claimed a method for identifying a potentially useful drug compound, without actually reducing to practice the drug compound itself (see, e.g., page 1009 of 68 USPQ2d). The Court did not recognize that Housey had possession of the drug products claimed by Bayer. Similarly, in the instant situation, one skilled in the art would not have recognized Appellant *to have been in possession of the claimed products*, namely the genus of transformed maize plants containing a broad genus of fatty acid desaturase genes, which plants exhibit a distinguishable morphological phenotypic trait. As possession is also a written description issue, *Bayer* is eminently applicable to the instant situation.

With regard to the references appended to the amendment of 18 October 2004, the Examiner maintains that said references were published after the effective filing date of claims drawn to transformed maize plants in general. As the claims are drawn to transformed maize plants, these references are insufficient to prove that the instantly claimed invention was well-known in the art prior to Appellant's disclosure. The Written Description Guidelines mandate that Appellant's specification, as opposed to prior or contemporaneous art, provide an adequate written description of the claimed genus.

Furthermore, regarding the structural characteristics of the genes encoding fatty acid desaturases contained in the claimed transformed plants, the Examiner maintains that Fox et al cited by Appellant supports the Examiner's position. Fox et al teach that

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in plants, *most* fatty acid desaturases are membrane-bound, while *only one* is soluble (see, e.g., page 2486, column one, middle paragraph). Membrane-bound proteins have hydrophobic (water-repellant) domains, while soluble proteins have hydrophilic (water-seeking) domains. These different domains are caused by different amino acid sequences which are encoded by different nucleotide sequences. Neither Appellant's specification nor the prior art identify any conserved sequences between the soluble and membrane-bound fatty acid desaturases, or the genes encoding them. Moreover, Fox et al teach that *plant* fatty acid desaturases show "*no substantial homology*" to *animal* fatty acid desaturase enzyme sequences (see, e.g., page 2486, column one, last sentence of middle paragraph). Fox et al also teach that a diiron-oxo sequence *domain found in fatty acid desaturase enzymes* is common to various *unrelated enzymes catalyzing unrelated chemical reactions* (see, e.g., page 2490, column 1, middle paragraph).

It is noted that Appellant's claims encompass the genus of transformed maize plants comprising any gene from any source, including plants and animals, which encodes any fatty acid desaturase gene from any source, including plants and animals. Thus, Fox et al teach that there are no conserved structural features between the species of this broad genus, and no conserved features correlated with function, i.e. fatty acid desaturase activity or phenotypic change at the whole plant level.

Regarding the Tables in Appellant's specification, the Examiner does not dispute that Appellant has reduced to practice maize plants transformed with genes conferring resistance to chemical antibiotics or herbicides, and that Appellant has reduced to

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practice cultured maize cells containing other transgenes. One skilled in the art would have recognized Appellant to have been in possession of maize plants transformed with said known antibiotic or herbicide resistance genes. However, the instant claims are not drawn to such maize plants. Instead, the instant claims are drawn to maize plants transformed with a broad genus of fatty acid desaturase genes, none of which were disclosed or characterized in the specification, wherein said maize plants exhibit distinguishing morphological traits as a result of the expression of said fatty acid desaturase genes. One skilled in the art would not have recognized Appellant to have been in possession of the instantly claimed maize plants, irrespective of their success in obtaining maize plants transformed with known genes encoding single proteins which confer resistance to toxic chemicals in a straightforward manner.

35 USC 112(1): Enablement

Claims 2-4 and 67 on appeal stand rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claims are *broadly drawn* to the genus of fertile maize plants transformed with *the genus of any gene encoding any fatty acid desaturase enzyme*, wherein the enzymes and genes are from any source, including plant, bacteria, fungi or animals; wherein the enzymes and genes are of any sequence; and wherein any desaturase enzyme having any fatty acid as a substrate is contemplated. As discussed above,

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different types of fatty acid desaturase enzymes act at different positions in the fatty acid, act on different types of fatty acids with different lengths and different side groups, and act on many different fused compounds containing them (see page 4 of the Answer).

The claims also broadly recite that the presence of the transgene confers any distinguishable phenotype on the transformed maize plants and seeds, wherein the phenotype is not specified, and may include increased disease resistance, increased cold tolerance, increased plant height, increased yield, increased insect resistance, altered carbohydrate content, increased drought tolerance, or changes in the color of flowers, fruits or leaves, etc.

In contrast, the specification does not provide guidance for the isolation or identification of even a single gene from a single source and of a single sequence which encodes any fatty acid desaturase as recited in claim 67 and dependents. The specification does not provide guidance for plant transformation with any fatty acid desaturase gene. The specification does not demonstrate that any putatively transformed plant possessing the claimed transgenes would exhibit an altered phenotype of any kind. The specification merely lists enzymes thought to be involved in fatty acid synthesis, including fatty acid desaturases as suggested on page 45, lines 27-29, and suggests plant transformation therewith. The specification does not even recite other publications which teach genes encoding such enzymes, and does not attempt to incorporate by reference their teachings.

The process of altering fatty acid composition in transformed plants, even when in possession of isolated genes encoding enzymes involved in fatty acid biosynthesis, is unpredictable. Post-Beittenmiller (1989) et al teach that transformation with an acyl carrier protein gene *failed to produce any detectable phenotypic change* in fatty acid synthesis or accumulation, even though acyl carrier protein is involved in fatty acid biosynthesis in native plants (see, e.g., page 889, Abstract).

Furthermore, Stephanopoulos et al (1993) teach that plant transformation for the modification of fatty acid accumulation generally has not been successful, that few eukaryotic organisms have had their metabolic pathways successfully altered, and that such alteration of metabolic pathways and accumulated metabolic products is limited by lack of knowledge of the rate limiting step, the existence of multiple rate limiting steps, and the evolved resistance of metabolic pathways to change even when a single enzyme or single step is altered (see, e.g., page 392, Abstract; paragraph bridging pages 392 and 393; page 393, paragraph bridging the columns; page 394, paragraph bridging the columns and the bottom two paragraphs of column 2; page 395, top paragraph; page 396, column 1, bottom paragraph).

Moreover, given the *unpredictability* inherent in merely modifying fatty acid synthesis in plants transformed with a gene encoding an enzyme involved therein, *it is highly unlikely* that plant transformation with fatty acid desaturase genes would *cause a multitude of phenotypes* unrelated to fatty acid type or content, such as changes in flower color, plant height, etc., as encompassed by the claims.

Given the claim breadth, unpredictability and lack of guidance as discussed above, undue experimentation would have been required by one skilled in the art to identify and isolate a multitude of non-exemplified fatty acid desaturase genes from a multitude of non-exemplified sources, to transform maize plants therewith, and to evaluate and obtain transformed maize plants with any type of altered phenotype following said transformation.

Appellant's Arguments

Appellant urges that the enablement rejection is improper, given the inapplicability of the case law cited by Examiner, the improper dismissal by the Examiner of declaratory evidence submitted with the amendment of 18 October 2004, the irrelevance of the transformation method or particular genes used by declarant Ursin to obtain transformed maize, the inapplicability of Appellant's rebuttal of a rejection over the prior art, and Appellant's examples in the specification (see pages 10-14 of the Brief of 24 July 2006). It is submitted that Appellant's arguments are not persuasive.

The Examiner maintains that *Genentech* is eminently applicable to the instant fact pattern. In *Genentech*, the Court found that claims directed to a method of cleaving undisclosed conjugate proteins were not enabled by a specification which merely suggested the desirability of such cleavage, given the disclosure of a DNA molecule encoding a particular human growth hormone, together with the knowledge in the prior art of "cleavable fusion expression techniques" (see, e.g., paragraph bridging pages 1003 and 1004 of 42 USPQ2d, page 1004, penultimate paragraph; and the sentence bridging pages 1004 and 1005). The Court found invalid a claim drawn to a method

involving a cleavage process which encompassed a known species of cleavage enzyme, when that method involved the combination of the cleavage process with a new protein to which it had not been previously applied.

In the instant situation, Appellant has not provided any specific DNA molecule encoding even one fatty acid desaturase, even though Appellant now asserts that such DNA sequences were known in the prior art. Even assuming *arguendo* that such DNA sequences were known in the prior art, the Court in *Genentech* found the prior knowledge of trypsin as a potential cleavage agent insufficient to enable the claimed invention. Appellant has provided even less information than the *Genentech* patent which the Court ultimately found invalid. The combination of a novel plant species for transformation, coupled with an allegedly known gene sequence, as instantly claimed, mirrors the claims found invalid in *Genentech*.

With regard to the Ursin declaration, the Examiner maintains that the experiment related therein involved the use of a non-exemplified method of maize transformation, as well as the simultaneous of two different fatty acid desaturase genes, one of which had been mutated (see, e.g., paragraph 5 of the Ursin declaration of 18 October 2004). The Examiner agrees that the claimed invention is the genus of maize plants which have been transformed with a genus of fatty acid desaturase genes, wherein said maize plants exhibit a distinguishable phenotype. The Examiner has provided ample evidence, in the form of scientific publications, that *prior to and at the time of Appellant's invention*, no one had successfully obtained transformed plants which exhibited an altered phenotype due to the introduction of genes encoding fatty acid biosynthesis

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enzymes. The state of the prior art provided no guidance regarding which experimental parameters were needed to overcome these obstacles, *and the instant specification provides none*. Thus, Ursin's use of non-exemplified transformation techniques, multiple genes, and mutated genes, *none of which were available prior to or at the time of Appellant's invention*, is eminently germane to the enablement of the claims.

Furthermore, the Examiner maintains that *Appellant confirmed the veracity of the Examiner's arguments* regarding the lack of enablement of the claimed invention, and the veracity of the evidence he cited to support his position . On page 9 of the Response of 18 October 2004, Appellant stated that "[t]he past failures of others are expressly documented in the enablement rejection in the Action itself, as well as in the references provided with the Action." This statement is not diminished by the fact that it appeared in the context of a rebuttal of a prior art rejection.

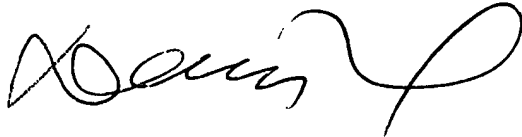
Regarding the evidence provided by Appellant's specification, the Examiner maintains that *no evidence has been provided* for the obtention of any transformed maize plant *containing any fatty acid desaturase gene*, whether or not the expression of said gene conferred any of a multitude of phenotypic traits, as instantly claimed.

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Conclusion

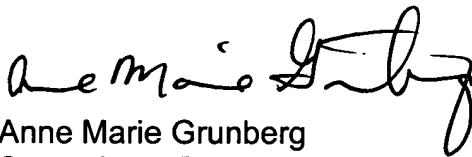
For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,



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